510(k) Summary K090092 APR 21 2009 000018

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: December 1, 2008

1. Company making the submission:

	Submitter
Name	VERICOM Co., Ltd.
Address	#606, 5th Dongyoung Venturestel 199-32, Anyang 7-Dong, Manan-Gu Anyang-Si, Gyeonggi-Do, Republic of Korea 430-817
Phone	+82 31 441-2881
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Contact	Myung-Hwan Oh
Internet	mh-oh@hanmail.net

2. Device :
   Proprietary Name – Well-Paste™
   Common Name – Root canal filling Materials
   Classification Name – Resin, Root Canal Filling

3. Predicate Device :
   Metapaste, META BIOMED CO. LTD. K032605

4. Description :
   Well-Paste™ is a temporary root canal filling material after endodontic surgery as pulp capping, pulpotomy or apexification. It contains Calcium Hydroxide and Barium Sulfate mainly, so it shows excellent radiopacity. It also has high fluidity and excellent accessibility into the root canal. Well-Paste™ is premixed paste as a non-setting material and is very stable without any solidification or separation. And it is packaged in a convenient syringe with disposable tips, a plastic holder and disposable tip cap.

5. Indication for use :
   Well-Paste™ is a biocompatible root canal sealer used for the temporary filling of root canal after endodontic surgery. Well-Paste™ can be used on its own and for vital pulpectomies in deciduous teeth.

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6. Review :

Well-Paste™ has the similar technological characteristics as the predicate device; device design, appearance, main materials and indication for use.

Well-Paste™ has the similar physical properties as the predicate device; flow, film thickness, radiopacity, solubility and disintegration.

Well-Paste™ has been subjected to extensive safety, performance, and product validations prior to release. Safety tests including biocompatibility have been performed to ensure the devices comply with the applicable International and US regulations.

7. Conclusions :

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification Vericom Co., Ltd. concludes that Well-Paste™ is safe and effective and substantially equivalent to predicate devices as described herein.

8. Vericom Co., Ltd. will update and include in this summary any other information deemed seasonably necessary by the FDA.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 21 2009

Vericom Company, Limited
C/o Mr. Marc M. Mouser
Responsible Third Party Official
Underwriters Laboratories, Incorporated
2600 NW Lake Road
Camas, Washington 98607-9526

Re: K090992
Trade/Device Name: Well-Paste™
Regulation Number: 21 CFR 872.3820
Regulation Name: Root Canal Filling Resin
Regulatory Class: II
Product Code: KIF
Dated: March 12, 2009
Received: April 7, 2009

Dear Mr. Mouser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., MA
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

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510(k) Number K 090992

Device Name: Well-Paste™

Indication for use:

Well-Paste™ is a biocompatible root canal sealer used for the temporary filling of root canals after endodontic surgery. Well-Paste™ can be used on its own and for vital pulpectomies in deciduous teeth.

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21CFR801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K090992